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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/577,032	04/20/2006	David Clayton Gantner	DC5183 PCT 1	9136
	7590 03/30/201 IG CORPORATION C		EXAM	INER
2200 W. SALZBURG ROAD P.O. BOX 994			MAZUMDAR, SONYA	
MIDLAND, MI	I 48686-0994		ART UNIT	PAPER NUMBER
			1745	
			NOTIFICATION DATE	DELIVERY MODE
			03/30/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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	Application No.	Applicant(s)	
	10/577,032	GANTNER ET AL.	
Office Action Summary	Examiner	Art Unit	
	SONYA MAZUMDAR	1745	
The MAILING DATE of this communication a Period for Reply	ppears on the cover sheet wit	h the correspondence address	
A SHORTENED STATUTORY PERIOD FOR REP WHICHEVER IS LONGER, FROM THE MAILING - Extensions of time may be available under the provisions of 37 CFR after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory perions after six or extended period for reply within the set or extended period for reply will, by state the maximum statutory perions after the maximum statutory perions after the maximum statutory perions of the state	DATE OF THIS COMMUNIC 1.136(a). In no event, however, may a re of will apply and will expire SIX (6) MONT oute, cause the application to become ABA	ATION. ply be timely filed HS from the mailing date of this communication. NDONED (35 U.S.C. § 133).	
Status			
1) ☐ Responsive to communication(s) filed on <u>15</u> 2a) ☐ This action is FINAL . 2b) ☐ The solution of the practice of t	nis action is non-final. vance except for formal matte	•	
Disposition of Claims			
4) ☐ Claim(s) 3-5,7 and 19-38 is/are pending in the day Of the above claim(s) is/are withdrest is/are withdrest claim(s) 20-24,26,28,30 and 35-38 is/are allest claim(s) 3-5,7,19,25,27,29,31-34 is/are reject claim(s) is/are objected to.	rawn from consideration. owed. cted.		
Application Papers			
9) The specification is objected to by the Examination The drawing(s) filed on is/are: a) and a continuous applicant may not request that any objection to the Replacement drawing sheet(s) including the correct of the continuous and the continuous and the correct of the continuous and the correct of the continuous and the continuo	ccepted or b) objected to be drawing(s) be held in abeyand ection is required if the drawing(s	ee. See 37 CFR 1.85(a). s) is objected to. See 37 CFR 1.121(d).	
Priority under 35 U.S.C. § 119			
12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of: 1. Certified copies of the priority docume 2. Certified copies of the priority docume 3. Copies of the certified copies of the priority docume application from the International Bure * See the attached detailed Office action for a list	nts have been received. nts have been received in Apiority documents have been eau (PCT Rule 17.2(a)).	oplication No received in this National Stage	
Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)	ummary (PTO-413) /Mail Date	
3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>2/14/2011</u> .	5) Notice of In 6) Other:	ormal Patent Application	

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DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed February 15, 2011 have been fully considered but they are not persuasive.

2. In response to applicant's argument that there is no teaching, suggestion, or motivation to combine the references, the examiner recognizes that obviousness may be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988), *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992), and *KSR International Co. v. Teleflex, Inc.*, 550 U.S. 398, 82 USPQ2d 1385 (2007).

In this case, it is clear that Colas et al. (EP 0955347) teach applying at least an adhesion promoter on the surface of a silicone gel (paragraph 0028), and it is agreed that Colas et al. fail to teach what type or how much of an adhesion promoters should be used. Applicants argue that Gantner et al. (US 6,512,702) do not teach treating the surface of a film-forming silicone gel on a sheet, but rather teaches applying additive in a film-forming composition. However, upon initial application of the additive, the surface of the film-forming composition is essentially be "treated", which reads on the claim.

If the claim limitation "treating a surface" has a more specific definition than how it is currently being interpreted, in view of carrying out the steps, then the claim should be amended to clarify the invention.

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Thus, the rejection of the claims is maintained.

Information Disclosure Statement

3. The information disclosure statement filed February 14, 2011 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. There is neither a copy nor English translation submitted for Japanese document 03-106977.

Claim Rejections - 35 USC § 103

- 4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 5. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
 - 1. Determining the scope and contents of the prior art.
 - 2. Ascertaining the differences between the prior art and the claims at issue.
 - 3. Resolving the level of ordinary skill in the pertinent art.
 - 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
- 6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

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under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 3, 4, 5, 7, 19, 25, 27, 29, 31, and 34 are rejected under 35 U.S.C. 103(a) as being obvious over Colas et al. in view of Gantner et al.

With respect to claims 19 and 31, Colas et al. teach a method of adhering a silicone gel to a substrate, comprising the steps of (abstract):

casting and curing a layer of a silicone gel on a sheet (paragraph 0028); treating the silicone gel with an adhesion promoter (paragraph 0025); applying the silicone gel to a carrier (paragraph 0028); removing the sheet from the silicone gel (paragraph 0028); and applying the silicone gel to a substrate to which the silicone gel is adhered to (abstract; paragraph 0015).

Colas et al. teach applying a silicone gel to a carrier sheet (i.e. first substrate), via a casting (i.e. transfer) method, where an additional adhesive or adhesion promoter (i.e. primer) may be used or even included in the gel, to bond the gel and the carrier sheet, and thus, would have been obvious for one having ordinary skill in the art to treat the surface of the silicone gel when applied to a first substrate (paragraphs 0019, 0025, and 0028); the gel may then be cured following application to the carrier (paragraphs 0030 and 0031). "Where the result accomplished is substantially the same, steps taken

concurrently or simultaneously are the equivalent of and not patentable over steps taken successively." (New Wrinkle v. Watson 96 USPQ 436)

Also, Colas et al. do not specifically teach treating silicone gel on a sheet with a specific primer. However, it would have been obvious for one having ordinary skill in the art to do so, as Gantner et al. is cited to teach treating a silicone gel with various agents and/or additives, including titanates and siloxanes, to make a product suitable for its end use. Furthermore, it would have been obvious that the agent is not mixed into the composition initially, since mixing of the component materials in the formulation causes curing at room temperature in the presence of moisture (column 1, lines 6-50; column 3, lines 56-65; column 5, line 47 – column 6, line 42).

With respect to claims 3 and 7, Colas et al. in view of Gantner et al. teach using a carrier or prosthesis of various types of plastic films, such as polyurethanes or silicones (Colas: paragraph 0012).

With respect to claim 4, Colas et al. in view of Gantner et al. teach using a prosthesis (i.e. carrier) of various materials, such as breast prosthesis, incontinence devices, pouches, tubes and other devices (Colas: paragraph 0037; Applicant's specification: paragraph 0017).

With respect to claim 5, Colas et al. in view of Gantner et al. teach applying a silicon gel layer with a thickness in the range of 0.2 mm to 5 mm (Colas: paragraph 0023).

With respect to claim 25, Colas et al. in view of Gantner et al. teach applying silicone gel with a tack in the range of 50 and 500 g. (Colas: paragraph 0024)

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With respect to claims 27, 29, and 34, Colas et al. in view of Gantner et al. teach applying a primer, diluted in alcohol or hexamethyldisiloxane, by brushing and other various methods (Colas: paragraphs 0031 and 0032; Gantner: column 4, lines 32-38; column 7, lines 33-34).

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8. Claims 3, 4, 5, 7, 19, and 25 are rejected under 35 U.S.C. 103(a) as being obvious over Colas et al. in view of Miyoshi et al. (JP 03-106977)

With respect to claim 19, Colas et al. teach a method of adhering a silicone gel to a substrate, comprising the steps of (abstract):

casting and curing a layer of a silicone gel on a sheet (paragraph 0028); treating the silicone gel with an adhesion promoter (paragraph 0025); applying the silicone gel to a carrier (paragraph 0028); removing the sheet from the silicone gel (paragraph 0028); and applying the silicone gel to a substrate to which the silicone gel is adhered to (abstract; paragraph 0015).

Colas et al. teach applying a silicone gel to a carrier sheet (i.e. first substrate), via a casting (i.e. transfer) method, where an additional adhesive or adhesion promoter (i.e. primer) may be used or even included in the gel, to bond the gel and the carrier sheet, and thus, would have been obvious for one having ordinary skill in the art to treat the surface of the silicone gel when applied to a first substrate (paragraphs 0019, 0025, and 0028); the gel may then be cured following application to the carrier (paragraphs 0030 and 0031). "Where the result accomplished is substantially the same, steps taken

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concurrently or simultaneously are the equivalent of and not patentable over steps taken successively." (New Wrinkle v. Watson 96 USPQ 436)

Also, Colas et al. do not specifically teach treating silicone gel on a sheet with a specific primer. However, it would have been obvious for one having ordinary skill in the art to do so, as Miyoshi et al. is cited to teach applying a primer to a silicone gel with various agents and/or additives, including siloxanes (e.g. diorganopolysiloxane and organo-hydrogeno-polysiloxane), where the primer is capable of forming a chemical bond to the silicone gel to be bonded to the support surface and provides good even adhesive strength and excellent performance as buffer from vigorous motions (abstract).

With respect to claims 3 and 7, Colas et al. in view of Gantner et al. teach using a carrier or prosthesis of various types of plastic films, such as polyurethanes or silicones (Colas: paragraph 0012).

With respect to claim 4, Colas et al. in view of Miyoshi et al. teach using a prosthesis (i.e. carrier) of various materials, such as breast prosthesis, incontinence devices, pouches, tubes and other devices (Colas: paragraph 0037; Applicant's specification: paragraph 0017).

With respect to claim 5, Colas et al. in view of Miyoshi et al. teach applying a silicon gel layer with a thickness in the range of 0.2 mm to 5 mm (Colas: paragraph 0023).

With respect to claim 25, Colas et al. in view of Miyoshi et al. teach applying silicone gel with a tack in the range of 50 and 500 g. (Colas: paragraph 0024)

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9. Claims 32 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Colas et al. in view of Gantner et al., as applied to claim 31 above, and further in view of Johnson.

The teachings of claim 31 are as described above.

Although Colas et al. do not specifically teach treating silicone gel on a sheet with a specific primer, it would have been obvious for one having ordinary skill in the art to do so, as Johnson et al. teach the use of tetra-n-butyl titanate and trimethoxymethylsilane as well-known coupling agents (Johnson: claims 1, 6, 7, and 15).

Allowable Subject Matter

10. Claims 20-24, 26, 28, 30, and 35-38 are allowed.

Although Colas et al. teach the following steps of adhering a silicone gel to a substrate:

casting and curing a layer of a silicone gel on a sheet (paragraphs 0028); applying the silicone gel on the sheet to a carrier (paragraph 0038); removing the sheet from the silicone gel (paragraph 0028); and applying the silicone gel to a substrate to which the silicone gel is adhered to (abstract; paragraph 0015);

Colas et al. do not specifically teach treating a sheet surface or a surface of a first substrate with a primer selected from titanate materials, zirconate materials, Si--H containing siloxanes and platinum materials.

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Conclusion

11. Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on February 14, 2011 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS**MADE FINAL. See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SONYA MAZUMDAR whose telephone number is (571)272-6019. The examiner can normally be reached on Monday-Friday, 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Philip Tucker can be reached on (571) 272-1095. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sonya Mazumdar/ Patent Examiner, Art Unit 1745